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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,687	12/22/2000	Peter Gill	7500.355US01	9767

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/14/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,687

Applicant(s)

Gill et al

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 20, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-9 and 11-41 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-9 and 11-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9 6) ☐ Other:

Art Unit: 1655

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on December 22, 1999. It is noted, however, that applicant has not filed a certified copy of the British application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 102

2. The rejections under 35 U.S.C. 102 are withdrawn in view of the amendment.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1655

4. Claims 2-8, 11-14, 16-20, 33, 34, 36, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weir et al (J. Forensic Science (1997) 42(2):213-222) in view of Krawczak (Electrophoresis (1999) 20:1676-1681).

Weir teaches a method for indicating that a DNA mixture from sources of a defined type where the DNA mixture is formed by DNA samples from more than one source (see page 216, column 2 where Weir discusses two contributors to mixture) comprising:

- a) determination of the identity of the alleles present at a locus for the DNA in the mixture (page 214, column 1) where Weir states "The evidentiary sample is ... found to have alleles abcd",
- b) determining a first probability function for the situation where the DNA mixture is formed from samples arising from the given person and from a first other person, for example either the victim and suspect or suspect and unknown (page 218, table 6, page 217, column 1 and page 214, column 1),
- c) determining a second probability function for the situation where the DNA mixture is formed from samples arising from a second other person and a first other person, for example a first and second perpetrator or two unknown contributors (page 214, column 1, page 217, column 1 and page 218, table 6),
- d) using the first probability function as a numerator and the second probability function as the denominator in determining the likelihood ratio for the mixture having arisen from

Art Unit: 1655

the defined type of sources considered in the first probability function (page 214, column 1, equations 1 and 2, as well as page 216, column 1, equation 4 and page 219, column 1),

e) determining such likelihood ratio for a plurality of loci (page 213, column 1, see “we assume independence of alleles, within and between loci”).

f) combining the likelihood ratio to give a combined likelihood ratio for the mixture having arisen from the defined type of sources considered in the first probability function (page 216, column 1, equations 3 and 4).

Weir teaches the use of databases which provide the frequency of occurrence of possible allele combinations that generate the identified allele identities for loci (page 213, column 2, “databases are available from which to estimate the frequencies of components of the profile”).

Weir does not teach application of the forensic analysis method to the use of single nucleotide polymorphisms.

Krawczak teaches that SNPs are superior in forensic analysis to earlier technologies and that SNPs can be subject to fast multiplex typing (page 1676, column 2). Krawczak further teaches the use of up to 30 SNPs representing 30 different loci (page 1679, table 2).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the SNPs of Krawczak in the place of RFLP loci of Weir since Krawczak states “SNPs may supersede microsatellites as the work horse of forensics since SNPs are more robust in terms of laboratory handling, data interpretation, stability of inheritance and population genetic analysis. One major advantage of SNPs is their amenability to fast, semi-

Art Unit: 1655

automatic multiplex tping (page 1676, column 2)". An ordinary practitioner would recognized that Krawczak provides a number of significant motivations to perform the analytical method of Weir using SNPs including improved speed, improved quality of data and improved robustness in laboratory handling.

5. Claims 2-9, 11-14, 16-34, 36, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weir et al (J. Forensic Science (1997) 42(2):213-222) in view of Krawczak (Electrophoresis (1999) 20:1676-1681) and further in view of Jarjoura et al (J. Forensic Science (1994) 39:64-73).

Weir in view of Krawczak teaches the limitations of claims 2-8, 11-14, 16-20, 33, 34, 36, 38 and 41 as discussed above. Weir expressly teaches a variety of loci contributors including a mixture which includes BB, BB (see table 1, column 1) as well as various mixtures of alleles (see table 5) and provides the frequency of these mixtures under either p^2 or $2p$ (see table 5). Weir provides for the three allele situation as well in which mp will necessarily equal 9 (see table 6).

Weir in view of Krawczak do not teach the multiplication of likelihood ratios.

Jarjoura teaches multiplication of the likelihood ratios in order to obtain a combined likelihood ratio (page 71, paragraph 2, "the product of the Lrs in table 1, was 1.6 implying such evidence is inconclusive").

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to multiply the likelihood ratios of Weir in view of Krawczak for multiple loci as taught by Jarjoura since Jarjoura teaches that multiplication of the likelihood ratios to form

Art Unit: 1655

a combined likelihood ratio yields more accurate assessments of the actual likelihood of a match in forensic testing. An ordinary practitioner would have been motivated to multiply likelihood ratios in order to improve the accuracy of the determination of match or mismatch of the particular individual being suspected of paternity or crime.

6. Claims 2-9 and 11-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weir et al (J. Forensic Science (1997) 42(2):213-222) in view of Krawczak (Electrophoresis (1999) 20:1676-1681) and further in view of Jarjoura et al (J. Forensic Science (1994) 39:64-73) and further in view of Chakraborty (Am. J. Hum. Gen. (1994) 55:391-401).

Weir in view of Krawczak and further in view of Jarjoura teaches the limitations of claims 2-9, 11-14, 16-34, 36, 38 and 41 as discussed above. Weir in view of Krawczak and further in view of Jarjoura do not teach analysis of Null alleles, which represent possible background noise..

Chakraborty teaches analyzing the Null alleles to correctly determine the independence of alleles in forensic analysis (see abstract, page 391, columns 1 and 2). Chakraborty teaches determining a probability where there is a null allele (see page 394, column 2) in which either the observed proportion or an unbiased estimate can be used (see page 394, column 2) and exemplifies this analysis (see table 2, page 396).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize null allele analysis of Chakraborty in the forensic method of Weir in view of Krawczak and further in view of Jarjoura since Chakraborty teaches "Specifically, we indicate that a statistical genetic method, originally suggested by Gart and Nam

Art Unit: 1655

(1984a), can be applied to examine the presence of nondetectable alleles in a DNA database (page 392, column 1)". Chakraborty also notes "Finally, we note that, although the theory discussed here is formulated in terms of the RFLP protocol of DNA typing, the existence of null alleles may also apply to PCR based scoring of alleles (page 399, column 2)". Chakraborty concludes "The theory described here can be used for such databases as well, when the origin of such nonamplification of alleles is not so thoroughly examined (page 400, column 1)". Thus, an ordinary practitioner would have been motivated to apply the null allele calculation of Chakraborty to the forensic SNP method of Weir in view of Krawczak and further in view of Jarjoura since Chakraborty expressly recognizes that null alleles may represent problems in PCR databases such as those of Krawczak and that statistical analysis can resolve this problem.

Response to Arguments

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1655

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman, Ph.D. whose telephone number is (703) 308-6568.

The examiner is normally in the office between the hours of 6:30 a.m. and 4:00 p.m., and telephone calls either in the morning are most likely to find the examiner in the office.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



Jeffrey Fredman

**JEFFREY FREDMAN
PRIMARY EXAMINER**